DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

November 14, 2014

Axiobionics, LLC
Attn: Ms. Nancy Lincé
Regulatory Affairs Consultant for Axiobionics, LLC
6111 Jackson Road
Suite 200
Ann Arbor, MI 48103

Re: K141342
Trade Name: AxioBionics Wearable Therapy Garments
Regulation Number: 21 CFR 882.1320
Regulation Name: Cutaneous electrode
Regulatory Class: Class II
Product Code: GXY
Dated: October 13, 2014
Received: October 15, 2014

Dear Ms. Lincé:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Felipe Aguel -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological and
Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141342

Device Name
AxioBionics Wearable Therapy Garments

Indications for Use *(Describe)*
The AxioBionics® Wearable Therapy® Garments with cutaneous electrodes are intended to be used to apply electrical stimulation current to the patient's skin via electro conductive media gel.

Example of electrical stimulation applications of the garment are:
a) Transcutaneous Electrical Nerve Stimulation (TENS) for pain relief

b) Neuromuscular Electrical Stimulation (NMES) for:

- Relaxation of muscle spasms
- Prevention or retardation of disuse atrophy
- Increasing local blood circulation
- Muscle re-education
- Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis
- Maintaining or increasing range of motion

c) Functional Electrical Stimulation (FES)

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

510(k) Summary

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

A. Name, Address, Phone and Fax Number of Applicant

AxioBionics, LLC
6111 Jackson Road, Suite 200
Ann Arbor, MI 48103
Philip Muccio, President
Phone: 734-327-2946
Fax: 734-327-3715

B. Contact Person

Nancy Lincé, President
Lincé Consulting
Phone: (650) 759-6186
nlince@linceconsulting.com

C. Date Prepared

October 13, 2014

D. Device Name

Trade Name:	AxioBionics® Wearable Therapy Garments
Common Name:	Cutaneous Electrode
Classification Name:	Electrode, cutaneous (21 CFR§ 882.1320, Product Code GXY)

E. Predicate Devices

The AxioBionics® Wearable Therapy Garments are substantially equivalent to:

- Bioflex Garments, Assorted Models (K944543)

F. Device Description

The AxioBionics Wearable Therapy Garments are garments that are made of nylon/spandex and neoprene fabric that hold and position the system's electrodes. Channels are built into the garments to allow the wiring of the electrodes to be managed for the patient. The garments can be worn as produced or altered (tailored) as needed for user fitment. The conducting element is contained in a positionable electrode for electro-conductivity. The gel permeable electrode pocket is on the inside of the garment. The garment is re-usable and washable as is the electrode

G. Indications for Use

The AxioBionics® Wearable Therapy® Garments with cutaneous electrodes are intended to be used to apply electrical stimulation current to the patient's skin via electro-conductive media gel.

Examples of electrical stimulation applications of the garment are:
a) Transcutaneous Electrical Nerve Stimulation (TENS) for pain relief
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- Maintaining or increasing range of motion

c) Functional Electrical Stimulation (FES)

H. Technological Comparison

Manufacturer	AxioBionics, LLC	AxioBionics, LLC
Device Name	Wearable Therapy Garments	Bioflex Garments
510(k) Number	K141342	K944543
Intended Use	Provide repeatable placement of multiple electrodes to conduct electrical stimulation from commercially available nerve stimulation devices to the patient's skin. Single patient use (re-usable, re-positionable).	Same
Product Code	GXY	Same
Resistivity/Impedance (electrode)	≤10 ohm	Not specified
Electrode Area (surface area in contact with skin)	1-600 in^2	Not specified
Average Tissue Electro-conductive Media Gel	Commercially available electro-conductive media gel	Same
Conductive Electrode Element	Silver Fabric or Silver Paper	Silver Fabric

Manufacturer	AxioBionics, LLC	AxioBionics, LLC
Device Name	Wearable Therapy Garments	Bioflex Garments
510(k) Number	K141342	K944543
Electrode Top Cover	Non-conductive Vinyl spandex – with one layer of spandex with vinyl layer	Non-conductive Vinyl spandex – with two layers of spandex (one on both sides with vinyl layer between)
Electrode Lead Wire	Single conductor cable, 24 AWG tinned copper conductors with PVC jacket	Same
Electrical Energy Patient Preparations for electrode placement	Not applicable – electrode contained within garment	Same
Electrode Placement	Positionable placement within garment	Fixed placement within garment
Max No. of Electrodes/Garment	40	Same
Usage	Disposable	Same
Replacement Electrode Packaging	Sealed Pouch	Same
Replacement Electrodes per Package	2	Not specified
Latex Content	Not made with natural rubber latex	Same

I. Summary of Non-Clinical Performance Testing

Dispersion testing has demonstrated that the electrodes used in the AxioBionics Wearable Therapy Garments have uniform current distribution with no evidence of "hot spots" that could cause patient discomfort or injury. The predicate electrodes used in the AxioBionics Bioflex Garment were included in the dispersion testing for comparison purposes. Additional comparison testing to the predicate device electrodes included simulated use, high-resolution dispersion evaluation, impedance, and wash cycles. Additional testing was performed on the subject device to assess the domatrode-to-electrode connection performance. Test results demonstrated that the AxioBionics Wearable Therapy Garments electrodes perform as intended and did not raise any new issues of safety or efficacy when compared to the predicate device electrodes.

J. Conclusion

AxioBionics considers the AxioBionics Wearable Therapy Garment electrodes to be substantially equivalent to the predicate device listed above. This conclusion is based on the similarities in primary intended use, principles of operation, functional design, non-clinical test results, and established medical use.